DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 25, 2015

Tides Medical
J. Doug Payne
VP Product Development
1819 West Pinhook Road, Suite 109
Lafayette, Louisiana 70508

Re: K143479
Trade/Device Name: Bluefin™ Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: August 27, 2015
Received: August 31, 2015

Dear Mr. Payne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143479

Device Name
Bluefin™ Interbody System

Indications for Use *(Describe)*

Lumbar Spine:

The Bluefin™ Interbody Cages – Lumbar are indicated for use with autograft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Bluefin™ Interbody Cages – Lumbar are intended to be used with supplemental spinal fixation systems, such as pedicle screws. Patients should be skeletally mature and have six (6) months of non-operative therapy prior to treatment with an intervertebral cage.

Cervical Spine:

The Bluefin™ Interbody Cages – Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Bluefin™ Interbody Cages – Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft. Bluefin™ Interbody Cages – Cervical are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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dpayne@tidesmedical.com
Phone: (888) 494 4441

Date Prepared: September 24, 2015

B. **Device Name**

Trade or Proprietary Name:	Bluefin™ Interbody System
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device - Cervical Intervertebral Body Fusion Device - Lumbar
Device Class:	Class II
Classification:	21 CFR § 888.3080
Product Code:	MAX/ODP

C. Predicate Devices

The subject Bluefin™ Interbody System is substantially equivalent to the primary predicate device, BAK™ Interbody Fusion System, BP/Lordotic Device: Sulzer Spine-Tech (P950002) and additional predicate devices LUMBAR I/F Cage® System: Depuy Acromed (P960025), Crystal® Intervertebral Body Fusion Device: Spinal Elements, Inc. (K073351), Lucent Intervertebral Body Replacement: Spinal Elements, Inc. (K071724) and CoRoent Lumbar System, NuVasive (K151472)

D. Device Description:

The Bluefin™ Interbody System consists of a variety of hollow vertebral body spacers designed for use in the cervical and lumbar spine. The device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine and cervical spine. It is available in heights from 5 - 12mm

The Bluefin™ Interbody Cervical Cage was developed for anterior cervical fusion. It is available in various footprints from 14 x 12mm up to 17 x 14mm and at 0 and 7 degree lordosis. The cages are trapezoidal in shape and includes x-ray markers for positioning. The subject device is made in various lengths and are designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance

The Bluefin™ Posterior Lumbar Interbody Cage (PLIF) were developed as an implant for the posterior stabilization of the lumbar spinal column. These cages feature a convex bullet nose design and an axial void designed to hold autograft material. The subject device is made in various lengths and are designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The devices range from 7mm to 16mm in height and 23mm to 37mm in length. The width varies from 9 to 11mm.

The Bluefin™ Transforaminal Lumbar Interbody Fusion (TLIF).Cage was developed as an implant for the posterior stabilization of the lumbar spinal column. The Bluefin™ TLIF cage is a banana-shaped implant featuring a convex, bullet nose design and an axial void designed to hold autograft material. The subject device is made in various lengths and are designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The devices range from 7mm to 16mm in height and footprints of 11 x 28 up to 13 x 37 mm. All the cages incorporate an A/P lordotic angle of 5 degrees.

The Bluefin™ Anteriar Lumbar Interbody Fusion (ALIF).Cage was developed as an implant for the anterior stabilization of the lumbar spinal column. The cages footprint is oval in shape and features a center beam for additional strength. The leading edge is bulleted for ease of insertion and features angular teeth for endplate grip and resist expulsion. The devices range from 8mm to 22mm in height and footprints of 30 x 24 up to 47 x 30 mm. All the cages incorporate an A/P lordotic angle of 6 or 12 degrees.

The Bluefin™ Lateral Lumbar Interbody Fusion (LLIF).Cage was developed as an implant for a lateral approach to the lumbar spine. The cages footprint are rectangular in shape and features a center beam for additional strength. The leading edge is bulleted for ease of insertion and features angular teeth for endplate grip and resist expulsion. The devices range from 8mm to 16mm in height and footprints of 18 x 50 up to 22 x 60 mm All the cages incorporate an A/P lordotic angle of 0 or 6 degrees.

The Bluefin™ devices are manufactured from Medical Grade PEEK (Polyetheretherketone) Zeniva® Polymer Solvay™ per ISO 10993-1 USP Class VI and ASTM F2026. The tantalum rods are manufactured from Grade UNS R05200 material according to ASTM F560.

E. Intended Use:

The Bluefin™ Interbody Cages – Lumbar are indicated for use with autograft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Bluefin™ Interbody Cages – Lumbar are intended to be used with supplemental spinal fixation systems, such as pedicle screws. Patients should be skeletally mature and have six (6) months of non-operative therapy prior to treatment with an intervertebral cage.

The Bluefin™ Interbody Cages – Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Bluefin™ Interbody Cages – Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft. Bluefin™ Interbody Cages – Cervical are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

F. Technological Characteristics

As was established in this submission, the subject Bluefin™ Interbody System are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Testing

The following tests were performed in this submission:

1. Static Compression per ASTM 2077
2. Dynamic Compression fatigue per ASTM F2077
3. Static Torsion per ASTM 2077
4. Dynamic Torsion fatigue per ASTM F2077
5. Static Expulsion per ASTM F1839-08
6. Subsidence per ASTM F2267
7. Wear Debris Analysis

H. Conclusions

Based on the technological characteristics, comparison to predicate devices, and performance data, the subject Bluefin™ Interbody System has been shown to be substantially equivalent to legally marketed predicate devices.